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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,644	01/22/2004	Noa Zerangue	019282-001511US	8428
20350 7590 05/15/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER CHANDRA, GYAN	
			ART UNIT 1646	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/763,644

Applicant(s)

ZERANGUE ET AL.

Examiner

Gyan Chandra

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10, 22 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 22, 29 and 32 is/are rejected.
- 7) ☐ Claim(s) 9, 10, 30 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Re: Zerangue et al.

Date of Priority: 10/08/2002 (US 60/417,298)

DETAILED ACTION

Applicants' response filed on 3/20/2007 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

The cancellation of claims 1-7, 11-21 and 23-28, and the addition of claims 29-32 have been made of record.

The amendments of claims 8-9 and 22 have been entered.

Claims 8-10, 22 and 29-32 are pending and under examination.

Response to Arguments

Specification

The objection that the disclosure on page 7 contains an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of Applicants' amendment of the specification.

Claim Rejections - withdrawn

Claim Rejections - 35 USC § 112, second paragraph

The rejection of claims 1-10 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicants amendments of claim 8-9, and the cancellation of claims 1-7.

Claim Rejections – maintained

Claim Rejections - 35 USC § 112-written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 remains rejected, and claims 22 (currently amended) and 29 and 32 (newly added) are now rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to an isolated polypeptide having an amino acid sequence at least 80% identical to an amino acid sequence set forth in SEQ ID NO: 2 over a region at least 40 amino acids in length or an isolated polynucleotide having a sequence that is at least 80% identical to a polynucleotide having SEQ ID NO: 1 over a region of at least 100 nucleotides in length, wherein the transporter specifically binds to an antibody that specifically binds to a polypeptide of SEQ ID NO:2.

Applicants argue (page 7 of Response) that (i) the disclosure identifies a relevant characteristic by disclosing that the polypeptide of SEQ ID NO: 2 is a transporter and that it has homology with Ost α and β transporters. Applicants argue that (ii) most obvious variant can be allelic variant, conservative variant and silent variants. Applicants argue that the polypeptide of SEQ ID NO: 2 transports taurocholate. Applicants argue that (iii) the skill in the art is high and one of skill in the art knows that transporters have a transporting domain, which is responsible for transporting a substrate through a plasma membrane (page 8).

Applicants' arguments have been fully considered but they are not persuasive because the specification does not disclose which domain and which amino acid residues are responsible for the transport activity of a transporter. Further, claims 8, 22 and 29 are not limited to only a particular domain of the polypeptide of SEQ ID NO: 2 rather they are drawn to any contiguous 40 amino acid residues of SEQ ID NO: 2 or any contiguous 100 nucleotides of the SEQ ID NO: 1. Therefore, one of skill in the art would not know which 20% amino acids could be changed while maintaining the transport activity of the polypeptide. Therefore, the written description does not provide support for any polypeptide having an amino acid sequence at least 80% identical to the amino acid sequence set forth in SEQ ID NO: 2 over a region at least 40 amino acids in length or any nucleic acid having a sequence that is at least 80% identical to the polynucleotide of SEQ ID NO: 1 over a region of at least 100 nucleotides in length, wherein the transporter specifically binds to an antibody that specifically binds to the polypeptide of SEQ ID NO:2.

Claim Rejections - 35 USC § 112-enablement

Claim 8 remains rejected, and claims 22 (currently amended) and 29 and 32 (newly added) are now rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 2 or the nucleic acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for any polypeptide having 80% sequence identity to the polypeptide of SEQ ID NO: 2 or any

nucleic acid having 80% sequence identity to the polynucleotide of SEQ ID NO: 1 for the reasons of record on pages 6-9 of the previous Office Action of 12/20/2006.

Applicants argue (page 9 of Response) that (i) the specification discloses that polypeptide of SEQ ID NO: 2 is a transporter and that a polypeptide of 80% variant should be a transporter. Applicants argue that (II) the art of transporters is very old and argue that a number of allelic and conservative variants of these transporters are generally known or in practice. Applicants argue that one of the skill in the art could use taurocholate or estron-3-sulfate as a substrate in screening assay for variants.

Applicants' arguments have been fully considered but they are not persuasive because the specification does not disclose which domain and which amino acid residues are responsible for the transport activity of a transporter and therefore, one of skill in the art would not know which amino acid(s) to mutate/change while maintaining the transport activity of the protein. Although, the skill making changes in a protein is high, predicting a change in a given polypeptide is still unpredictable (see the previously cited reference Skolnick et al., 2000, especially p. 36 at Box 2). Therefore, using taurocholate or estron-3-sulfate as a substrate in screening assay for variants would require large amount of experimentation, and making innumerable number of variants of the polypeptide of SEQ ID NO: 2 to the full scope of the instant invention. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 8 remains rejected, and claims 22 (currently amended) and 29 and 32 (newly added) are now rejected under 35 U.S.C. 102(e) as being anticipated by Kato et al (US Pub No.20040034192, priority date of 12/8/2000) for the reasons of record on page 9-10 of the previous Office Action of 12/20/2006.

Claims 8, 22 and 29 are drawn to a method of screening whether an agent, conjugate or conjugate moiety is a substrate of a transporter providing (i) a cell expressing a transporter having an amino acid sequence at least 80% identical to an amino acid sequence set forth in SEQ ID NO: 2 over a region at least 40 amino acids in length or an isolated polynucleotide having a sequence that is at least 80% identical to a polynucleotide having SEQ ID NO: 1 over a region of at least 100 nucleotides in length, (ii) contacting the cell with an agent, conjugate moiety or conjugate and (iii) determining whether the agent, conjugate moiety or conjugate passes through the transporter.

Applicants argue (page 10 of Response) that (i) the reference Kato does not teach that the protein of SEQ ID NO: 38 is a transport protein. Applicants argue that (ii) the reference in [305-307] only suggests that the polypeptides of SEQ ID NO: 122, 132 and 142 are similar to a mouse cation transport protein and that these sequences are not related to the SEQ ID NO: 38. Applicants argue that (iii) Kato only discloses in paragraph [223] that the protein of SEQ ID NO: 38 encodes for a 340 amino acid

residues comprising six transmembrane domains but the reference does not suggest that the polypeptide of SEQ ID NO: 38 is a transporter.

Applicants' arguments have been fully considered but they are not persuasive because Kato teaches cloning and expressing various secretory proteins or membrane proteins having hydrophobic domains and that these proteins can be used for identifying ligands in various screening assays (abstract). Kato teaches that membrane proteins play important roles of proteins such as signal receptors, ion channels, transporters or like that. Kato teaches that a transporter protein can be transporters for saccharides, amino acids or like that [0003]. The skill of the art is high (page 9 of Response). Further, Kato contemplates screening for ligands or small molecules suitable for pharmaceutical use which inherently could be a substrate for the polypeptide [0338]. Therefore, the prior art of record anticipates the instantly claimed invention, and the rejection is maintained.

Claims 9-10, and 30-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 8, 22, 29 and 32 are rejected.

Claims 9-10, and 30-31 are objected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.
Art Unit 1646
09 May 2007
Fax: 571-273-2922



GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600